

## **REMARKS**

The applicants appreciate the examiner's review of the prior art and request reconsideration of the pending claims in view of the following remarks. Applicants would also like to thank the examiner for finding claims 38, 43, 64, and 68 allowable if rewritten in independent form. Claim 87 has been cancelled. Claims 1, 4-7, 10-13, 16-24, 37, 38, 40-47, 49, 63-75, and 77-86, 88-92 are currently pending in the application.

## **Claim Objections**

The office action objects to claim 87 as being redundant because it contains only limitations cited in the independent claim. As mentioned above, applicants have cancelled claim 87. Therefore, applicants believe that this objection is now moot.

## **35 U.S.C. 102(b) Rejections**

The office action rejected claims 1, 4-7, 10-13, 16-24, 74, 75, 77-92 as being anticipated by US Patent Number 5,700,248 (Lopez, hereinafter "Lopez").

Claim 1 defines, in relevant part, a medical valve having a plug member supported by a gland and movably mounted within a passageway defined by a housing. The plug member includes a cannula defining a channel for directing fluid through the valve.

Lopez does not teach such a medical valve. Instead, Lopez has a stationary spike element 24 with openings 35 into a hollow portion. As a medical instrument is inserted into the Lopez valve, a seal 36 compresses axially within the housing causing the spike element 24 to pierce the seal 36. As the spike element 24 protrudes through the seal 35, the openings 35 are exposed, creating fluid communication between the medical instrument and the hollow spike. Nowhere does Lopez teach a moveably mounted plug, as required by claim 1.

The office action suggests that portions 94, 36a, and 98 of the seal 36 (as shown in Figure 9) constitute the moveable plug member. As a preliminary matter, the elements 94, 36a, and 98 are distinct regions of a single, unitary element; namely an elastomeric seal.

For the sake of discussion, however, without agreeing with the action's characterization, even if these portions could be considered a moveable plug member, they do not define a channel for directing fluid through the valve, as required by claim 1. Rather, to establish fluid communication, the medical instrument compresses and deforms the seal 36 and portions 94, 36a, and 98 to expose the openings 35. Portions below the openings 35, thus, are a dead end. Accordingly, at no point do portions 94, 36a, and 98 define part of the fluid channel. Instead, as mentioned in Lopez, the fluid channel is defined by the medical instrument, the hollow spike, and the inner conduit (Col. 6, lines 30-32) – it is not defined by any interior part of the seal 36. Accordingly, claim 1 is allowable over Lopez. Moreover, claims 4-7, and 10-12, which depend from claim 1, are allowable for at least the same reasons.

In a manner similar to claim 1, claims 74, 82, and 90 define a medical valve having a moveable plug member that either defines a channel for directing fluid through the valve (e.g., claim 82) or provides a portion of an unoccluded fluid path when the valve is open (e.g., claims 74 and 90). Accordingly, claims 74, 82, and 90 are allowable over Lopez for the same reasons as discussed above with regard to claim 1. Moreover, claims 75, 77-81, 83-86, 88-89, and 91-92, which depend from claims 74, 82, and 90, respectively, are also allowable for at least the same reasons.

Claim 13 defines, in relevant part, a medical valve having a housing defining a passageway, a plug member moveably mounted within the passageway, and a gland member secured about at least a portion of the plug member.

As discussed above, Lopez does not teach a moveable plug member. Instead, it has a stationary spike. Moreover, as noted above, the portion recited in the Office Action as the seal and post member simply is a single, unitary seal. For claim 13, this is evidenced, at least in part, by the fact that the gland portion 95 (as suggested in the Office Action) is not secured about at least a portion of portions 94, 36a, and 98. Rather, portions 94, 36a, and 98 are located distal to the so called gland 95 – no portion of the gland portion 95 is “secured about” portions 94, 36a, and 98. Therefore, the alleged gland 95 cannot meet the requirements of claim 13. Accordingly,

claim 13 is allowable over Lopez. Moreover, claims 16-24, which depend from claim 13, are allowable for at least the same reasons.

The office action rejected claims 37, 40-42, 44-47, 79, 63, 65-67, and 69-73 as being anticipated by US Patent Number 5,439,451 (Collinson, hereinafter “Collinson”).

Claim 37 defines, in relevant part, a medical valve having plug member that is moveably mounted in a passageway defined by a housing. The plug member is a cannula and has an opening nearer to its distal end. A resilient gland member normally occludes the opening within the plug member.

Collinson does not disclose a plug member having a cannula with an opening that is normally occluded by a gland member. As is known in the art, the term cannula describes a tube having two spaced openings. The plug 32 in Collinson is not a cannula. Rather, Collinson’s plug has a blind bore (a dead end) with only one opening. Accordingly, Collinson’s plug cannot constitute a cannula, as required by claim 37.

Moreover, even if Collinson’s plug could constitute a cannula, which, as discussed above, it cannot, the opening of the blind bore is not normally (i.e., when closed) occluded by a resilient gland member. In fact, the opposite is true – the opening to the blind bore normally is open.

The office action suggests, however, that the gland 30 normally occludes the opening via the tip 56 of the center post 54 – a rigid element. Primarily, the tip 56 is not part of the gland 30. Rather, the tip 56 is part of the rigid center post 54. Therefore, even if the tip 56 normally occluded the blind bore, the gland still would not normally occlude the opening because the tip 56 is not part of the gland 30. Furthermore, Collinson makes no mention of occluding the blind bore opening in any mode. Even the drawings show space around the tip 56, thus permitting air in and out of the bore. Accordingly, claim 37 is allowable over Collinson. Moreover, claims 40-42, 44-47, and 49, which depend from claim 37 are also allowable for at least the same reasons.

In a manner similar to claim 37, claim 63 defines a medical valve having a plug member with an opening that is normally occluded by the gland member. Accordingly, claim 63 is allowable over Collinson for the same reasons as discussed above with regard to claim 37. Moreover, claims 65-67, and 69-73, which depend from claim 63 are also allowable for at least the same reasons.

Applicants do not understand the comments of paragraph 5 of the Office Action.  
Clarification would be greatly appreciated.

All pending claims therefore are allowable over the cited art. The application therefore is in condition for allowance and such action is earnestly solicited. Applicants believe that a one month extension of time is required and hereby request that the associated fee and any additional fees required by this paper or credit any overpayment to Deposit Account No. 19-4972. Applicants also request that the examiner contact applicant's attorney, Jonathan Lovely, if it will assist in processing this application through issuance.

Respectfully submitted,

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